

CHAPTER 461 PHARMACISTS AND PHARMACY

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§461-1 Definitions. For the purposes of this chapter:

"Board" means the board of pharmacy of the State except where another meaning is clearly manifested by the context.

"Cosmetics", which includes "soap", "dentifrice", and "toilet article", means:

- (1) Articles intended to be rubbed, poured, or sprinkled on, introduced into, or otherwise applied to the human body, or any part thereof, for cleansing, beautifying, or promoting attractiveness; and
- (2) Articles intended for use as a component of any such articles.

"Director" means the director of commerce and consumer affairs.

"Drug" means:

- (1) Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

- (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;
- (3) Articles (other than food or clothing) intended to affect the structure or any function of the body of human beings or animals; and
- (4) Articles intended for use as a component of any articles specified in paragraph (1), (2), or (3) above; provided that the term "drug" shall not include devices or their components, parts, or accessories, cosmetics, or liquor as defined in section 281-1.

"Encumbered license" means a license issued by any state or territory of the United States for the practice of pharmacy which is revoked, suspended, or made probationary or conditional by the licensing or registering authority in the respective jurisdiction as a result of disciplinary action.

"Medical oxygen" means the prescription drug oxygen.

"Medical oxygen distributor" means any person, including a prescription drug wholesale distributor, who distributes or dispenses medical oxygen pursuant to a prescription.

"Pharmacy" means every store, shop, or place:

- (1) Where prescription drugs are dispensed or sold at retail, or displayed for sale at retail;
- (2) Where practitioners' prescriptions or drug preparations are compounded;
- (3) That has upon it, displayed within it, or affixed to or used in connection with it, a sign bearing the words "pharmacist", "pharmacy", "apothecary", "drug store", "druggist", "drugs", "medicines", "medicine store", "drug sundries", "remedies", or any words of similar or like import; or
- (4) Where any of the above words or combination of words are used in any advertisement.

The term "pharmacy" shall not include any medical oxygen distributor.

"Practice of pharmacy" means:

- (1) The interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices (except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially legend drugs and devices); the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records therefor; the responsibility for advising when necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices;
- (2) Performing the following procedures or functions as part of the care provided by and in concurrence with a "health care facility" and "health care service" as defined in section 323D-2, or a "pharmacy" or a licensed medical doctor, or a "managed care plan" as defined in section 432E-1, in accordance with policies, procedures, or protocols developed collaboratively by health professionals, including physicians and surgeons, pharmacists, and registered nurses, and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols:
 - (A) Ordering or performing routine drug therapy related patient assessment procedures;
 - (B) Ordering drug therapy related laboratory tests;
 - (C) Administering drugs orally, topically, or by injection, pursuant to the

patient's licensed medical doctor's order, by a pharmacist having appropriate training that includes programs approved by the American Council of Pharmaceutical Education (ACPE), curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;

- (D) Administering immunization by injection to persons eighteen years of age or older, by a pharmacist having appropriate training that includes programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy;
 - (E) As authorized by a licensed medical doctor's written instructions, initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's licensed medical doctor and related to the condition for which the patient has been seen by the licensed medical doctor; provided that the pharmacist shall issue written notification to the patient's licensed medical doctor or enter the appropriate information in an electronic patient record system shared by the licensed medical doctor, within twenty-four hours;
 - (F) Transmitting a valid prescription to another pharmacist for the purpose of filling or dispensing; or
 - (G) Providing consultation, information, or education to patients and health care professionals based on the pharmacist's training and for which no other licensure is required; and
- (3) The offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy.

"Licensed medical doctor" means a medical doctor licensed by the board of medical examiners pursuant to chapter 453 or the board of osteopathic examiners under chapter 460.

"Practitioner" means an individual licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the person's practice.

"Prescription" means an order or formula issued by a practitioner licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the practitioner's practice, for the compounding or dispensing of drugs or an order or formula issued by an out-of-state practitioner in compliance with chapter 328.

"Prescription drug" means any drug dispensed, distributed, or sold pursuant to a practitioner's order.

"Registered pharmacist" means a person licensed under this chapter to practice in a pharmacy except where another meaning is clearly manifested by the context.

§461-2 Board of pharmacy; appointment; qualifications. There shall be a board of pharmacy of seven members.

Five members of the board shall be graduates of a school or college of pharmacy and shall have been licensed as pharmacists and actively engaged in the practice of pharmacy for at least five years prior to their appointment and two shall be public members. Four members of the board shall be residents of the city and county of Honolulu and three shall be residents of counties other

than the city and county of Honolulu.

§461-3 Records. The executive secretary, subject to the direction of the board, shall make and keep all records and record books required to be kept by the board and shall furnish the department of health with copies of those records as it requires.

§461-4 REPEALED.

§461-4.5 Powers and duties. (a) In addition to any other powers and duties authorized by law, the board:

- (1) Shall adopt, amend, and repeal rules pursuant to chapter 91, as it deems proper for the purposes of this chapter, Public Law 100-293, and 21 Code of Federal Regulations part 205;
- (2) Shall examine, license, reinstate, and renew the licenses of qualified applicants for registered pharmacists and wholesale prescription drug distributors, and issue and renew permits to operate pharmacies;
- (3) May require the inspection of any wholesale prescription drug distributor premises in the State to ensure compliance with this chapter and rules adopted under this chapter, or may require an applicant for a pharmacy license to submit a statement that the premises, including but not limited to security and sanitation, are in conformance with the board's requirements and that the applicant possesses the reference materials and technical clinical equipment and supplies as may be specified in rules adopted under this chapter; and
- (4) May fine, suspend, or revoke any license or permit for any cause prescribed by this chapter, or for any violation of the rules adopted under this chapter, and refuse to grant or renew any license or permit for any cause which would be ground for revocation or suspension of a license or permit.

(b) Nothing in this chapter shall modify or limit any powers of the board or the department of health of this State.

§461-5 Qualifications for license. (a) Any applicant for a license as a pharmacist shall submit an application on a form prescribed by the board and shall provide evidence to the board that the applicant:

- (1) Is at least eighteen years of age;
- (2) Holds a degree from a school or college of pharmacy or department in a university which is recognized and accredited by the American Council of Pharmaceutical Education;
- (3) Has a minimum of fifteen hundred hours practical experience in any state of the United States in a pharmacy under the supervision of a registered pharmacist. Service and experience in a pharmacy under the supervision of a registered pharmacist as required in this section shall be predominantly related to the selling

of drugs, compounding prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes. In the event an applicant has no practical experience as required, the applicant may take the examination and upon passing the examination, shall not receive a license until after the fulfillment of the practical experience requirement;

- (4) Has passed an examination as may be prescribed by the board; and
- (5) Does not have an encumbered license or a pending disciplinary action or unresolved complaint in the practice of pharmacy in any state or territory of the United States, or if any license has been or is encumbered, the applicant shall provide all information requested by the board.

(b) Any applicant who is otherwise qualified to apply for a license to practice pharmacy in this State, but who is a graduate of a school or college of pharmacy located outside the United States which has not been recognized by the board as an accredited school, may be deemed to have satisfied the requirement of subsection (a)(2) by providing verification to the board of the applicant's academic record and graduation and by meeting other requirements as the board may establish from time to time. The board shall require the applicant to successfully pass an examination or examinations given or approved by the board to establish proficiency in English if the school is located outside the United States in a country where the official language is not English, and equivalency of education of the applicant with qualified graduates of a school or college recognized by the board as a prerequisite to taking the licensure examination required by section 461-6.

§461-6 Examination; license. (a) Every applicant for a license as a pharmacist shall meet all qualifications set by the board including, but not limited to, passing all examinations as prescribed by rules of the board. The board shall determine the passing score for each examination.

(b) Every applicant for a license as a pharmacist, except an applicant applying under section 461-8.5, shall apply on a form to be supplied by the board and shall either file the form with the board at least sixty days before the examination, or if taking the examination in another state pursuant to the National Association of Boards of Pharmacy Score Transfer Program, shall file the form no later than ninety days after the examination. Each application shall be accompanied by application and examination fees. The board shall establish the schedule for examinations.

(c) Each applicant who successfully passes each required examination and meets all other requirements of the board shall pay a license fee.

(d) An applicant who fails an examination shall file an application for reexamination in the examination for which a passing score was not achieved and shall not be licensed until the applicant successfully passes all of the licensure examinations.

§461-7 Temporary license. (a) A registered pharmacist of any state or territory of the United States who does not have an encumbered license or any pending disciplinary action or unresolved complaints in any state or territory of the United States and who is not eligible for licensure by reciprocity under section 461-8.5 may be granted a temporary license by the board;

provided that the person shall first pass a jurisprudence examination as required by the board.

(b) A temporary license shall not entitle the holder to a permanent license, and no permanent license shall be issued until the person has passed the remaining licensure examinations set forth in section 461-6. Only one temporary license shall be issued to the same applicant.

(c) A temporary license shall only remain in effect until the results of the next licensure examinations are announced; provided that the board may extend any temporary license, upon written request, for good and just cause. Any applicant who fails to take or to pass the next licensure examination shall surrender the temporary license. The board shall receive a fee for the issuance of a temporary license.

§461-8 Renewal of licenses. (a) All licenses issued by the board, except temporary licenses issued under section 461-7, shall be renewed biennially on or before December 31 of each odd-numbered year. Failure to pay the biennial fee shall constitute a forfeiture of the license as of the date of expiration.

(b) Any license forfeited pursuant to subsection (a) may be restored within three years upon payment of any penalty fee, the current biennial fees, and the renewal fee for the next biennium, if applicable, and meeting any other requirements specified in rules adopted pursuant to chapter 91.

(c) In the event that the pharmacist has not engaged in the practice of pharmacy in this State or in another state or territory of the United States within the past five years, the board may require the pharmacist to satisfy additional requirements, as specified in rules adopted pursuant to chapter 91, to demonstrate that the pharmacist is competent to practice in this State.

§461-8.5 Reciprocity. (a) Any pharmacist who is registered or licensed under the laws of any state or territory of the United States with qualifications for licensure which equal or exceed those of this State, shall be eligible for licensure; provided that:

- (1) The pharmacist possesses a current valid license;
- (2) The pharmacist has practiced as a registered pharmacist for fifteen hundred hours or more within the five years preceding the date of application;
- (3) There is no disciplinary action pending or other unresolved complaints against the pharmacist in any state or territory of the United States;
- (4) The pharmacist does not have an encumbered license or a pending disciplinary action or unresolved complaint in the practice of pharmacy in any state or territory of the United States, or if any license has been or is encumbered, the pharmacist shall provide any information requested by the board; and
- (5) The laws of the other state or territory grant reciprocal treatment to licensees of this State.

The board may examine these licensees only as to knowledge of this State's statutes and rules.

(b) An applicant applying for licensure pursuant to this section shall provide proof that the standards upon which licensure was granted by another state or territory of the United States are at least equivalent to the licensing standards that were in effect in this State under sections 461-5 and 461-6 at the time licensure in the other state or territory was granted.

(c) An applicant for reciprocity who is unable to demonstrate that licensure was based

on standards at least equal to those in sections 461-5 and 461-6, may be issued a temporary license while fulfilling requirements necessary for licensure in this State. The requirements and limitations of a temporary license shall be the same as those under section 461-7.

§461-8.6 Wholesale prescription drug distributor license. It shall be unlawful for any person to operate, maintain, open, change location, or establish any wholesale prescription drug distribution business within the State without first having obtained a license from the board.

§461-9 Pharmacist in charge; pharmacy personnel. (a) A registered pharmacist shall be in personal and immediate charge of the pharmacy and personnel employed in the pharmacy. Temporary absences of the registered pharmacist shall be unlawful except for periods of time and under circumstances as authorized under the rules of the board. During any absence of the registered pharmacist, prescriptions may not be filled, compounded, or received by telephone and no drugs shall be sold; provided that this shall not preclude the sale at those times of things that might be sold were the pharmacy a store not subject to this chapter. No person other than a registered pharmacist or a pharmacy intern under the registered pharmacist's immediate supervision shall fill or compound prescriptions except as provided by subsection (c).

(b) No person shall practice as a pharmacy intern without having first obtained a permit from the board. The board shall adopt rules pursuant to chapter 91 defining the functions of a pharmacy intern, establishing the requirements to be met by an applicant for a pharmacy intern permit, and specifying the duration of the permit and the procedures for the immediate supervision of the pharmacy intern by a registered pharmacist.

(c) A pharmacy technician may be employed to assist the registered pharmacist under rules adopted by the board pursuant to chapter 91 that define the qualifications and functions of the pharmacy technician and provide the procedures for control and supervision by a registered pharmacist.

§461-10 Pharmacies. Any proprietor or manager of a pharmacy who fails or neglects to place a registered pharmacist in charge thereof or who permits the compounding of prescriptions, or the vending of drugs, except by or under the immediate supervision of a registered pharmacist, shall be deemed to have violated this chapter. Any person who, not being a registered pharmacist, compounds prescriptions or vends drugs, while not subject to the immediate supervision of a registered pharmacist, shall be deemed to have violated this chapter.

§461-11 Duties of registered pharmacist. Every registered pharmacist in charge of a pharmacy shall comply with all laws and rules. The pharmacist shall be responsible for the management of the pharmacy and every activity thereof which is subject to this chapter shall be under the pharmacist's complete control.

All registered pharmacists shall notify the board of changes of business address within ten days.

§461-12 Adequate equipment. A pharmacy that compounds drugs shall be equipped with adequate pharmaceutical equipment to ensure the proper compounding of prescriptions. The board shall by rules prescribe the minimum of professional and technical equipment and reference materials that a pharmacy shall at all times possess.

§461-13 Prescription record. A pharmacy shall keep prescription records of each prescription compounded or dispensed at the pharmacy for a period of not less than five years. The prescription records shall at all times be open to inspection by the board of pharmacy and other law enforcement officers.

§461-14 Permits for operation of pharmacy. (a) It shall be unlawful for any person to operate, maintain, open, change location, or establish any pharmacy within the State without first having obtained a permit from the board.

(b) Application for permits shall be made on a form to be prescribed by the board. Separate application shall be made and separate permits issued for each separate place at which is carried on any of the operations for which a permit is required.

(c) On evidence satisfactory to the board a permit shall be issued, provided:

- (1) That the pharmacy for which the permit is sought is or will be, in full compliance with this chapter and rules of the board;
- (2) That the location and appointments of the pharmacy are such that it can be operated and maintained without endangering the public health or safety; and
- (3) That the pharmacy will be under the personal and immediate supervision of a registered pharmacist.

(d) No application for a permit shall be refused except pursuant to this section and only after notice to the applicant and a full and fair hearing.

§461-15 Miscellaneous permits. (a) It shall be unlawful:

- (1) For any person to sell or offer for sale at public auction, or to sell or offer for sale at private sale in a place where public auctions are conducted, any prescription drugs without first obtaining a permit from the board of pharmacy to do so;
- (2) For any person to distribute or dispense samples of any prescription drugs without first obtaining a permit from the board to do so; provided that nothing in this paragraph shall interfere with the furnishing of samples or drugs directly to physicians, druggists, dentists, veterinarians and optometrists for use in their professional practice;
- (3) For wholesalers to sell, distribute, or dispense any prescription drug, except to a pharmacist, physician, dentist, veterinarian, or optometrist who is allowed to use pharmaceutical agents under chapter 459 or to a generally recognized industrial, agricultural, manufacturing, or scientific user of drugs for professional or business purposes; provided that it shall be unlawful for wholesalers to sell, distribute, or dispense any prescription pharmaceutical agent that is not approved by the board examiners in optometry;

- (4) For any wholesale prescription drug distributor to sell or distribute medical oxygen except to a:
 - (A) Licensed practitioner with prescriptive authority;
 - (B) Pharmacist;
 - (C) Medical oxygen distributor;
 - (D) Patient or a patient's agent pursuant to a prescription; or
 - (E) Emergency medical services for administration by trained personnel for oxygen deficiency and resuscitation;
- (5) For any medical oxygen distributor to supply medical oxygen pursuant to a prescription order, to a patient or a patient's agent, without first obtaining a permit from the board to do so; and
- (6) For any person, as principal or agent, to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first obtaining a permit from the board to do so; and
- (7) For any out-of-state pharmacy or entity engaging in the practice of pharmacy, in any manner to distribute, ship, mail, or deliver prescription drugs or devices into the State without first obtaining a permit from the board; provided that the applicant shall:
 - (A) Provide the location, names, and titles of all principal corporate officers;
 - (B) Attest that the applicant or any personnel of the applicant has not been found in violation of any state or federal drug laws, including the illegal use of drugs or improper distribution of drugs;
 - (C) Submit verification of a valid unexpired license, permit, or registration in good standing to conduct the pharmacy in compliance with the laws of the home state and agree to maintain in good standing the license, permit, or registration; and
 - (D) Have in its employ a registered pharmacist whose registration is current and in good standing.
- (b) A person whose application for a permit has been denied may file an administrative hearing in conformity with chapter 91.

§461-16 Fees for permits and licenses; renewal. (a) The board shall collect application, license, and permit fees for each permit to operate a pharmacy or for each license to operate as a wholesale prescription drug distributor and a fee for the issuance of a permit in accordance with section 461-15(a)(1), (5), (6) and (7).

(b) Permits issued under sections 461-14 and 461-15 and licenses issued under section 461-8.6 shall be conspicuously displayed in the place for which the permit or license was granted. The permits and licenses shall not be transferable, shall expire on December 31 of each odd-numbered year following the date of issuance, and shall be renewed biennially.

(c) The holder of an expired permit or an expired license to operate as a wholesale prescription drug distributor may have the same restored within three years of the date of expiration upon due application therefor and payment of the delinquent fees and a penalty fee; provided that in the case of an expired permit, the holder of the expired permit meets the requirements for the renewal of permits.

§461-16.5 REPEALED.

§461-17 Penalties. Any person violating this chapter or the rules duly prescribed by the board of pharmacy shall be fined not more than \$500, or imprisoned not more than six months, or both.

§461-18 Right of injunction. The department may, in addition to any other remedies available, apply to a court having competent jurisdiction for an injunction to restrain any violation of this chapter.

§461-19 Application of law. This chapter shall not apply to any practitioner legally licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the practitioner's practice when the practitioner is handling drugs in the course of the practitioner's professional duties or prohibit the practitioner from personally supplying the practitioner's own patients with such prescription drugs if the prescription drugs fall within the practitioner's scope of authorized practice.

§461-20 Poison law not amended. Nothing in this chapter amends chapter 330.

§461-21 Disciplinary action. (a) In addition to any other actions authorized by law, the board shall have the power to deny, revoke, or suspend any license or permit applied for or issued by the board in accordance with this chapter, and to fine or otherwise discipline a licensee or permit holder for any cause authorized by law, including but not limited to the following:

- (1) Procuring a license through fraud, misrepresentation, or deceit;
- (2) Professional misconduct, gross carelessness, or manifest incapacity;
- (3) Permitting an unlicensed person to perform activities which require a license under this chapter;
- (4) Violation of any of the provisions of this chapter or the rules adopted pursuant thereto;
- (5) Violation of any state or federal drug, controlled substance, or poison law;
- (6) False, fraudulent, or deceptive advertising;
- (7) Any other conduct constituting fraudulent or dishonest dealings;
- (8) Failure to comply with a board order;
- (9) Making a false statement on any document submitted or required to be filed by this chapter; or
- (10) Habitual intemperance or addiction to the use of habit-forming drugs.

(b) Any person who violates any of the provisions of this chapter or the rules adopted pursuant thereto shall be fined not less than \$100 nor more than \$1,000 for each violation.

(c) All proceedings for denial, suspension, fine, or revocation of a license or permit on any grounds specified in subsection (a) shall be conducted pursuant to chapter 91, including the right of judicial review.

[§461-22] Cumulative remedies. The remedies or penalties provided by this chapter are cumulative to each other and to the remedies or penalties available under all other laws of this State.